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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/886,954	06/21/2001	Maureen J. Charron	96700/667	6743
	7590 06/16/2004		EXAMINER NICKOL, GARY B	
Craig J. Arnold, Esq. AMSTER, ROTHSTEIN & EBENSTEIN 90 Park Avenue New York, NY 10016			ART UNIT 1642	

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/886,954

Applicant(s)

CHARRON ET AL.

Examiner

Gary B. Nickol Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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Re: Charron *et al.*

Date of priority: June 21, 2001

***Response to Amendment***

The Amendment filed 03/25/2004 in response to the Office Action of 12/30/2003 is acknowledged and has been entered.

Claims 1-20 are pending and are currently under consideration.

**The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.**

**Rejections Maintained:**

Claims 1-20 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of record in the Action mailed 12-30-2003. The written description in this case only sets forth a method for determining whether a subject has *endometrial* cancer comprising assaying for GLUTx expression. Thus, the written description is not commensurate in scope with the claims drawn to detecting GLUTx expression in a genus of neoplastic-like cellular conditions.

Applicants argue (Response filed 3-25-04, page 6) that the specification supports the disclosure for a genus of hyperplasias, pre-neoplastic lesions and neoplasms because in addition to endometrial cancers, working examples are provided in the specification

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for metastasizing and non-metastasizing rodent adenocarcinomas breast cancer cells and mouse mammary tumors that were generated by over expression of oncogenes. This argument has been considered but is not found persuasive. The claims are drawn to methods for determining whether a subject has a defect in cell proliferation, comprising assaying a diagnostic sample of the subject for GLUTx expression, wherein detection of GLUTx expression elevated *above normal* is diagnostic of the defect. However, the written description only reasonably conveys the quantification of GLUTx expression (above normal) in one particular species of cancer- endometrial adenocarcinomas (page 43, lines 5+). Thus, although Applicants have argued that the specification indicates that GLUTx is also expressed in certain rodent breast cancers, there is no comparison or description of GLUTx expression in *normal* rodent breast and or mammary tissues. Thus, the written description does not support the scope of the claimed subject matter drawn to determining a genus of cancerous conditions by detecting GLUTx expression wherein detection of GLUTx expression is elevated above normal. Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

Claims 1-20 remain rejected under 35 U.S.C. 102(e) as being anticipated by Baughn *et al.* (US 2003/0171275 A1, December 20, 2000) for the reasons of record.

Applicants argue (page 7) that the reference does not specifically disclose that expression of a polypeptide having the sequence set forth in SEQ ID NO:1 is elevated above normal when a subject has a hyperplasia, a pre-neoplastic lesion, or a neoplasm. This argument has been considered but is not found persuasive. Any elevation above normal or compared to a standard is an inherent consequence of the methods taught in the

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prior art wherein Baughn *et al.* teach that quantities of TRICH (TRICH polypeptides encompass the claimed SEQ ID NO:1) expressed in subject, control, and disease samples from biopsied tissues are compared with the standard values and that “deviation between standard and subject values establishes the parameters for diagnosing disease” (para 247).

Applicants further argue that the reference of Baughn *et al.* does not enable the present invention. Applicants argue that, at best, Baughn *et al.* present an invitation to experiment to determine which TRICH is under expressed or over expressed in association with which disorder. This argument has been considered but is not found persuasive. A reference contains an “enabling disclosure” if the public was in possession of the claimed invention before the date of invention. “Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his [or her] own knowledge to make the claimed invention.” In re Donohue, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985). Further, MPEP 2136.05 lists the guidelines for overcoming a rejection under 35 U.S.C. 102(e) which does *not* include arguing that the reference is not enabling. Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

**All other rejections and or objections are withdrawn in view of applicant's amendments and arguments there to.**

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri., 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary B. Nickol Ph.D.  
Primary Examiner  
Art Unit 1642

June 10, 2004



**GARY NICKOL  
PRIMARY EXAMINER**